

U.S.S.N. 09/732,411

Filed: December 7, 2000

AMENDMENT AND RESPONSE TO OFFICE ACTION UNDER 37 C.F.R. § 1.116

**Remarks****Rejection Under 35 U.S.C. § 112, first paragraph**

Claims 1, 3-5, 7 and 16-18 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Claim 1 has been amended to recite that the method is for inhibiting binding of a cell to collagen, glycosaminoglycan, fibrinogen, fibronectin, collagen, vitronectin, thrombospondin, osteopontin, bone sialoprotein 1, von Willebrand's factor or vascular adhesion molecule and includes providing the cell with a peptide molecule comprising a peptide having a molecular weight between 100 and 2500 Daltons and consisting of a sequence selected from the group consisting of SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:12, SEQ ID NO:14 and SEQ ID NO:15. Support for this amendment is found on page 3, line 15 and lines 23-29; page 8, lines 17-21; page 19, lines 21-22; and page 20, lines 5-8.

This amendment should be entered since it narrows the scope of the claim, is responsive to rejections made in the office action, and would remove issues from appeal.

Claim 17, directed to inhibiting the binding of a cell within a human subject, has been canceled.

As the examiner has correctly noted, claim 1 does not recite administration to a human, although the language does not exclude it. That fact that there may not be proof that the method works in all situations is not sufficient to make the claim non-enabled. It is very clear the claim is enabling *in vitro* and in cell culture, and the studies provided here are of the type to be reasonably predictive of success in an animal, based on

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comparisons to other similar situations. There are many peptides that are routinely administered to an individual for use in blocking binding, including RGD peptides and inhibitors of selectins. The facts in this application are quite similar to those situations. The examiner has provided no basis for the rejection other than that there is no animal or human data. This does not meet the legal standard. The legal standard for lack of enablement requires the examiner provide some factual basis for believing the claims are not enabled, not just an assertion that the claims are not enabled. The only basis here is unsupported assertion.

The claims, as amended, are enabled. Pages 5-8 and 19-20 fully describe the adhesion modulatory peptides, the mechanism by which they inhibit cell binding, and the cell types that are inhibited. In addition, compositions containing the peptide molecules are characterized on pages 20-24. Furthermore, the ability of the peptide molecules to inhibit cell binding to each of the recited substrates; collagen (page 19, lines 21-22), glycosaminoglycans (page 19, lines 29-31), fibrinogen, fibronectin, vitronectin, thrombospondin, osteopontin, bone sialoprotein 1, and von Willebrand's factor (page 20, lines 5-8 and page 8, lines 16-21), and integrins and vascular adhesion molecule (page 20, lines 1-4 and page 6, lines 6-16), is adequately disclosed in the specification. Finally, claim 1 has been limited to a method of inhibiting cell binding outside of a subject. The specification is indeed enabling for the *in vitro* use of the peptide molecules.

It is clear that one of ordinary skill in the art would be able to inhibit the binding of a cell to the recited substrates by providing the cell with a peptide molecule containing a peptide consisting of a sequence selected from the group consisting of SEQ ID NOs: 6-8, 10, 12, 14 and 15, without undue experimentation.

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Claims 1, 3-5, 7 and 16 and 18 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Claim 1 now recites that the peptide has a molecular weight between 100 and 2500 Daltons (page 3, line 15). This amendment should overcome the Examiner's rejection.

The claims to the elected species should be allowable. Examination of the full scope of the claims and allowance of claims 1, 3-5, 7 and 16 and 18, as amended, is respectfully solicited.

Respectfully submitted,

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